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Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111			EXAMINER PRYOR, ALTON NATHANIEL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/710,181
Filing Date: November 10, 2000
Appellant(s): JENSEN ET AL.

John Guynn
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/14/11 appealing from the Office action mailed 07/18/11.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
41,42,44-48,50-54,56-63,65-68,70-87, and 91-94.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,851,512	FISCHER	12-1998
6,306,370	JENSEN ET AL	10-2001
6,368,576	JENSEN ET AL	4-2002
6,309,625	STEVEN ET AL	10-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USPN 5851512; 12/22/98), Fischer teaches a dental composition comprising a desensitizing agent such as 0.1 – 10% potassium nitrate (column 3 line 35- column 4 line 36, column 8 lines 51-67). Fischer teaches fluoride salts such as sodium fluoride (column 9 lines 1-17), peroxides such as

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carbamide peroxide and hydrogen peroxide (column 9 lines 36-47) and antimicrobial agents (tetracycline) can be added to the composition for anticariogenic activity, bleaching effect, and antimicrobial activity, respectively (column 4 lines 38-51). Example 8 used 10% urea peroxide (column 8 line 62 – column 15 line 12). Glycerine, propylene glycol and carboxypolymethylene (tackifying agents) can be added so that the composition adheres to teeth (column 8 lines 1-22). Water may also be added to the composition in a range of 0-50% by weight of the dental composition. (column 8 lines 11-22). Fischer teaches that EDTA or citric acid can be added to the dental composition in order to preserve stability of the dental composition (column 9 lines 28-35. Fischer teaches a method of treating teeth with the dental composition (column 11 line 54 - column 12 line 7). Fischer teaches a method of applying the dental composition to teeth by using a dental tray. The tray can be left on teeth for 15 minutes, one hour, or for any desire time period (column 11 line 54 - column 12 line 7). The method does not require brushing for the dental composition to work (column 5 lines 44-57). Fischer differs from the instant invention in that Fischer does not explicitly teach an invention to a non-abrasive composition or a dental composition that is substantially abrasive free. However, Fischer does not teach anywhere in the specification that his invention comprises an abrasive. Therefore, it is obvious that Fischer's invention is non-abrasive or substantially abrasive free.

(10) Response to Argument

Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide

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peroxide(bleaching agent) plus 0.5% potassium nitrate(desensitizing agent). Appellants argue that potassium nitrate is a known desensitizing agent and that potassium nitrate reduces the sensitivity of carbamide peroxide(bleaching agent) on teeth. For this reason, Appellants point out that it is unexpected that 0.5% potassium nitrate(desensitizing agent) would be more effective in reducing the tooth sensitivity to 10.5% carbamide peroxide(bleaching agent) than 3% potassium nitrate since it would have been expected that more desensitizing agent would be more effective than less desensitizing. However, Appellants found the opposite to be true, i.e. 0.5% potassium nitrate is more effective than the 3% potassium nitrate in reducing tooth sensitivity to the bleaching agent carbamide peroxide at 10.5% concentration. Appellants argue that because 0.5% potassium nitrate unexpectedly yielded reduced oral sensitivity compared to when either 3% or 0% is used, it is within reason to conclude that amounts of potassium nitrate within narrowly tailored ranges on either side of 0.5% would yield greater desensitization compared to 3% or 0% potassium nitrate. Appellants argue that the nonobvious of a broader claimed range can be supported by unexpected data obtained from the testing of a narrower range. There is no case law that requires Appellants to only claim the specific species employed in the comparative study. The Examiner agrees with the Appellants. However, Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration

trend for potassium nitrate and carbamide peroxide. The example is not commensurate in scope with the claims, including claims 61 and 94.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12,15,16 of U.S. Patent No. 5851512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent. USPN '512 does not require an abrasive. Fischer differs from the instant invention in that Fischer does not claim an invention to a non-abrasive composition or a dental composition that is substantially abrasive free as

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claimed. However, Fischer does not teach anywhere in the specification that his invention comprises an abrasive. Therefore, it is obvious that Fischer's invention is non-abrasive or substantially abrasive free. Fischer differs from the instant invention in that Fischer does not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Fischer does suggest such an invention.

(10) Response to Argument

Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide peroxide(bleaching agent) plus 0.5% potassium nitrate(desensitizing agent). Appellants argue that potassium nitrate is a known desensitizing agent and that potassium nitrate reduces the sensitivity of carbamide peroxide(bleaching agent) on teeth. For this reason, Appellants point out that it is unexpected that 0.5% potassium nitrate(desensitizing agent) would be more effective in reducing the tooth sensitivity to 10.5% carbamide peroxide(bleaching agent) than 3% potassium nitrate since it would have been expected that more desensitizing agent would be more effective than less desensitizing. However, Appellants found the opposite to be true, i.e. 0.5% potassium nitrate is more effective than the 3% potassium nitrate in reducing tooth sensitivity to the bleaching agent carbamide peroxide at 10.5% concentration. Appellants argue that USPN '512 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '512 recites potassium nitrate concentration in claim 4 of "about 0.1 to about 10%" and in claim 5 "about 1 to about 7%". The ranges recited in the

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claims of '512 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues that Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,10-20 of U.S. Patent No. 6368576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

(10) Response to Argument

Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide peroxide(bleaching agent) plus 0.5% potassium nitrate(desensitizing agent). Appellants argue that potassium nitrate is a known desensitizing agent and that potassium nitrate reduces the sensitivity of carbamide peroxide(bleaching agent) on teeth. For this reason, Appellants point out that it is unexpected that 0.5% potassium nitrate(desensitizing agent) would be more effective in reducing the tooth sensitivity to 10.5% carbamide peroxide(bleaching agent) than 3% potassium nitrate since it would have been expected that more desensitizing agent would be more effective than less desensitizing. However, Appellants found the opposite to be true, i.e. 0.5% potassium nitrate is more effective than the 3% potassium nitrate in reducing tooth sensitivity to the bleaching agent carbamide peroxide at 10.5% concentration. Appellants argue that USPN '576 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '576 recites potassium nitrate concentration in claim 10 of "up to about 10%". The range recited in the claim 2 of '576 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a

concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,11,13-19,23-26 of U.S. Patent No. 6309625. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent. USPN '625 does not require an abrasive. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

(10) Response to Argument

Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide peroxide(bleaching agent) plus 0.5% potassium nitrate(desensitizing agent). Appellants argue that potassium nitrate is a known desensitizing agent and that potassium nitrate reduces the sensitivity of carbamide peroxide(bleaching agent) on teeth. For this reason, Appellants point out that it is unexpected that 0.5% potassium nitrate(desensitizing agent) would be more effective in reducing the tooth sensitivity to

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10.5% carbamide peroxide(bleaching agent) than 3% potassium nitrate since it would have been expected that more desensitizing agent would be more effective than less desensitizing. However, Appellants found the opposite to be true, i.e. 0.5% potassium nitrate is more effective than the 3% potassium nitrate in reducing tooth sensitivity to the bleaching agent carbamide peroxide at 10.5% concentration. Appellants argue that USPN '625 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '625 recites potassium nitrate concentration in claim 2 of "about 0.1 to about 50%". The range recited in the claim 2 of '625 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant

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application and patent discloses a method of applying a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

(10) Response to Argument

Appellants point to the Declaration of Dan Fischer filed 6/25/01 showing unexpected results for a dental composition comprising 10.5% carbamide peroxide(bleaching agent) plus 0.5% potassium nitrate(desensitizing agent). Appellants argue that potassium nitrate is a known desensitizing agent and that potassium nitrate reduces the sensitivity of carbamide peroxide(bleaching agent) on teeth. For this reason, Appellants point out that it is unexpected that 0.5% potassium nitrate(desensitizing agent) would be more effective in reducing the tooth sensitivity to 10.5% carbamide peroxide(bleaching agent) than 3% potassium nitrate since it would have been expected that more desensitizing agent would be more effective than less desensitizing. However, Appellants found the opposite to be true, i.e. 0.5% potassium nitrate is more effective than the 3% potassium nitrate in reducing tooth sensitivity to the bleaching agent carbamide peroxide at 10.5% concentration. Appellants argue that USPN '370 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '370 recites potassium nitrate concentration in claim 1 of "at

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least about 0.1%", in claim 2 "at least about 1 to about 7%" and in claims 14 and 16 "about 0.1 to about 10%". The ranges recited in the claims of '370 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues that Appellants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Alton N. Pryor/

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/SREENI PADMANABHAN/

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